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| 10/633,938 | 08/04/2003 | Kevin A. Kelly | D24-1d | 5790 |
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| 3764 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/633,938

Applicant(s)

KELLY ET AL.

Examiner

TAM NGUYEN

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128-134, 145-156, 171-182, 198-209, 212 and 228-239 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128-134, 145-156, 171-182, 198-209, 212 and 228-239 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/4/03 & 11/15/06 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "first and second opposite extremities" of the belt, the "contact with a substantial majority of a patient's chest", the "continuous contact" of the belt with the patient's "front, sides and a portion of the back", the "fastening" of the power unit to the belt, "fastening to an apparatus any of said extremities of said belt not already fastened to said apparatus", the "powered belt tightener coupled to said belt extremities", the first and second electrodes and the various types of motors must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The amendment filed June 26, 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: substantially subsection (A) of each of the independent claims. In particular, wrapping a belt around and "in contact with a substantial majority of a patient's chest near said patient's sternum, said belt being in continuous contact with the patient's chest, including the front, sides and a portion of the back of said patient's chest, said belt (1) extending around and being in contact with a major portion of the circumference of said chest, (2) extending around and being in contact with the front, sides and back of said chest."

Claim Objections

3. Claim 134 is objected to because of the following informalities:
Claim 134 discloses the same limitation as claim 133. This duplication appears to be a clerical error since both claims provide the same limitation. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 131, 132, 148, 149, 174, 175, 201, 202, 228 and 232 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The specification does not disclose a means for detecting when the belt means has placed a patient's chest under compression nor the inducement of a defibrillating electric current to the patient's chest at the time. Additionally, the specification does not disclose a means for detecting when the belt means has placed a patient's chest under maximal compression nor then inducement of a defibrillating electric current to the patient's chest at that time.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 128-134, 145-156, 171-182, 198-209, 212 and 228-239 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 128, it is not clear what is meant by the phrase, "first and second states." In claims 128 and 171, it is not readily apparent how the belt is moved in a direction to tighten the belt around the patient's chest. In claims 145 and 198, it is not readily apparent how the belt extremities are moved in directions to tighten the belt. In claim 228, it is not readily apparent how the belt is moved in a direction to tighten the belt around a patient's chest. The elected species shown in Figure 9 merely suggests a cable (256) connecting a power unit (254) to a belt (258). Claims 128, 145, 171, 198 and 228 each disclose the phrase "to perform CPR". This clause appears to be

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indefinite since CPR also require providing air/breath to the patient and that step is not included in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 128 and 129 remain rejected under 35 U.S.C. 102(b) as being unpatentable over Dedo '579 in view of Cook (3,503,388).

6. As to claims 128 and 129, Dedo discloses a device and inherently a method for CPR treating patients comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of a patient's chest (P) near said patient's sternum, said belt extending around and being in contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest, fastening/connecting to a power unit (72) said belt, placing an actuator (74) having first and second states in said first state to provide power from a power supply, such as a battery or outlet, to the power unit to repeatedly move the belt in a direction to tighten the belt around the patient's chest (see Fig. 9). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses a similar respiration appliance having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of

ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of the chest compression process since the belt will not stretch substantially.

Claims 130-134, 228-239 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dedo in view of Cook '388 and in further view of Barkalow et al. (4,273,114).

7. As to claims 130-134, Dedo and Cook disclose a modified method of performing CPR as described above (see discussion of claim 129). Dedo does not disclose that the method further includes defibrillating the torso of the patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two spaced outer chest surfaces are contacted with first and second electrodes. Barkalow discloses an apparatus and inherently a method of performing CPR that includes defibrillating the chest of a patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two spaced outer chest surfaces are contacted with first and second electrodes (48,75) (see Fig. 6, ABSTRACT & Col. 8, lines 13-45). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine Barkalow's step of simultaneous compression and defibrillation to Dedo's CPR method since the compression would shorten the path to the heart thereby reducing the power required to defibrillate the patient's heart.

8. As to claims 228-235 and 239, Dedo discloses a modified device and inherently a method for CPR treating patients comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of a patient's chest near said patient's sternum (P), said belt extending around and being in contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest and moving said belt in a direction to tighten the belt around the patient's chest to place the chest under compression with the belt extremities being moved substantially equally around the patient's left and right sides (see Fig. 9). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses a similar respiration appliance having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of the chest compression process since the belt will not stretch substantially. Dedo does not disclose that the method further includes defibrillating the torso of the patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two spaced outer chest surfaces are contacted with first and second electrodes. Barkalow discloses an apparatus and inherently a method of performing CPR that includes defibrillating the chest of a patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current

at that time wherein two spaced outer chest surfaces are contacted with first and second electrodes (48,75) (see Fig. 6, ABSTRACT & Col. 8, lines 13-45). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine Barkalow's step of simultaneous compression and defibrillation to Dedo's CPR method since the compression would shorten the path to the heart thereby reducing the power required to defibrillate the patient's heart.

9. As to claims 236-238, Dedo, Cook and Barakalow disclose a method for CPR as described above (see discussion of claim 234). Dedo does not disclose that the belt tightener includes a fluid-pressure motor, a hydraulic motor, or a pneumatic motor. The examiner takes Official Notice that the prior art includes medical devices that use a variety of motors for actuation of various components. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use any of an array of motors including those disclosed by the instant invention since they provide a readily usable and portable actuation force.

10. Claims 145, 146, 152-156, 171, 172, 178-182, 198, 199, 205-209 and 212 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dedo in view Cook '388 and in further view of Szpur (5,407,418).

11. As to claims 145, 146, 152 and 153, Dedo discloses a device and inherently a method for CPR treating patients comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of a patient's chest (P), said belt extending around and being in contact with a major portion of the circumference of said chest, extending around and being in contact with the front

sides and back of said chest and fastening/connecting to an apparatus/power unit (72) said belt (see Fig. 9).). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses a similar respiration appliance having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of of the chest compression process since the belt will not stretch substantially. Dedo does not disclose providing a signal to a powered belt tightener to move the belt extremities in directions to tighten the belt around the patient's torso. Szpur discloses a similar mechanism that provides a timed application of force to a belt wherein the signal is provided to a belt tightener to move the belt to tighten around a user (see Col. 4, lines 18-47). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute Dedo's belt tightening mechanism with Szpur's belt tightening mechanism such that Szpur's fittings (53 and 54 of hinge 40) are connected to Dedo's belt extremities 104 and 110 to allow for an electric motor controlled compression of the patient's torso since Szpur's mechanism allows for adjusting the time period of repeated compression and tightening of the belt substantially equally around the patient.

12. As to claims 171, 172, 178, 179, 198, 199, 205, 206 and 212, Dedo discloses a device and inherently a method for CPR treating patients comprising wrapping a belt/strap (24) with first and second opposite extremities around and in contact with a substantial majority of a patient's torso (P), said belt extending around and being in

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contact with a major portion of the circumference of said chest, extending around and being in contact with the front sides and back of said chest and fastening/connecting to the belt apparatus/power unit (72) (see Fig. 9). Dedo discloses that the belt is flexible but Dedo does not disclose that the belt is substantially inelastic. Cook discloses a similar respiration appliance having a compression belt (11) made from a substantially inelastic material (see Fig. 2 & Col. 2, lines 24-26). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to make Dedo's belt from a substantially inelastic material to improve the efficiency of of the chest compression process since the belt will not stretch substantially. Dedo does not disclose that power is supplied in regular intervals to the power unit to repeatedly tighten the belt around the patient's torso and that the power unit is adapted to receive power from an electrical source via a cable/line. Szpur discloses a similar belt tightening mechanism having an electrical power unit that is adapted to automatically receive power from an electrical source via a cable/line (128) in regular periodic intervals (see Fig. 3 & Col. 5, lines 9+). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to substitute Dedo's belt tightening mechanism with Szpur's belt tightening mechanism such that Szpur's fittings (53 and 54 of hinge 40) are connected to Dedo's belt extremities 104 and 110 to allow for an electric motor controlled compression of the patient's torso since Szpur's mechanism allows for adjusting the time period of repeated compression and tightening of the belt substantially equally around the patient's left and right sides.

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13. As to claims 154-156, 180-182 and 207-209, Dedo, Cook and Szpur disclose a modified method for CPR as described above (see discussion of claims 152, 178 respectively). Szpur does not disclose that the belt tightener includes a fluid-pressure motor, a hydraulic motor, or a pneumatic motor. The examiner takes Official Notice that the prior art includes medical devices that use a variety of motors for actuation of various components. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use any of an array of motors including those disclosed by the instant invention since they provide a readily usable and portable actuation force.

Claims 147-151, 173-177 and 200-204 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dedo in view Szpur and Cook and in further view of Barkalow et al. (4,273,114).

14. As to claims 147-151, 173-177 and 200-204, Dedo, Cook and Szpur disclose a modified method of performing CPR as described above (see discussion of claims 145, 146, 171 and 712). Dedo does not disclose that the method further includes defibrillating the torso of the patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two spaced outer chest surfaces are contacted with first and second electrodes. Barkalow discloses an apparatus and inherently a method of performing CPR that includes defibrillating the chest of a patient undergoing resuscitation, detecting when the belt has placed the patient's chest under maximal compression and inducing a defibrillating electric current at that time wherein two

spaced outer chest surfaces are contacted with first and second electrodes (48,75) (see Fig. 6, ABSTRACT & Col. 8, lines 13-45). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine Barkalow's step of simultaneous compression and defibrillation to Dedo's CPR method since the compression would shorten the path to the heart thereby reducing the power required to defibrillate the patient's heart.

Response to Arguments

15. Applicant's arguments filed June 25, 2008 have been fully considered but they are not persuasive.

As to the drawings, applicant argues that the claims under examination were generic to Figures 7-9; thus, species selection requirement was artificial and the various elements shown in Figs.7-9 can be drawn together to satisfy the requirements of 37 CFR § 1.83(a). This is erroneous unless the specification clearly provides a clause that states that elements from one species can be incorporated by another species. Since the specification does not disclose such a clause, the applicant is precluded from taking elements from one or more species and combining them with another species in an attempt to satisfy the requirements of 37 CFR § 1.82(a) for a particular species.

As to the specification, applicant appears to be arguing that the July 11, 2007 amendment did not introduce new matter when in fact it did. During the interview with Mr. Lach and the undersigned attorney on July 6, 2007, examiner attempted to work with the Mr. Lach and his attorney to obviate the Lach et al. '164 reference such that applicant's invention could be allowed. Unfortunately, claim language was agreed to

that would obviate the Lach reference but it was not discovered until later that said claim language was not supported by the specification and thus must be considered new matter. Once this discovery was made, the applicant was notified and provided with a non-final rejection so that applicant could properly respond to the new matter rejection. The applicant also argues that the last office action dated January 2, 2008 made clear that the ultimate objective of the office action was to refuse to allow the issuance of the present application. This is definitely not the case. In Paragraph 4 of the last Office Action dated January 2, 2008, the examiner merely laid out his plan for rejecting the claims when the new matter was removed to expedite the prosecution. It was the examiner's hope that by revealing the office's most likely course of action, the applicant would proceed in another direction to try to overcome the Lach reference or distinguish his invention from the prior art. Applicant also argues that the claim language, particularly the clauses of Subsection (A) of the independent claims is based on the actual disclosure but there is no support in the specification that the belt is wrapped around "in **continuous** contact with the patient's chest, including front, sides and a portion of the back of said patient's chest." In particular, applicant argues that the clause is supported by the figures, but Figure 9 of the elected Species does not support the clause.

As to the claim rejections under 35 U.S.C. § 112, applicant argues that since defibrillation constitute standard techniques in the art of resuscitating patients suffering from cardiac arrest, the particulars of defibrillation as part of the applicant's invention is not necessary. Examiner respectfully disagrees with this argument. Indeed the prior art

may disclose the combination of defibrillation and CPR, but applicant specifically claims a method wherein defibrillation occurs at maximal compression thus, applicant's particular process or step of determining maximal compression should be adequately disclosed. Applicant also argues that the two states of "on" and "off" or "forward" and "reverse" are not indefinite; however, there is no language in the specification to infer that the two states refer to "on" and "off" or "forward" and "reverse". That is, there is no language to preclude a person from concluding that the "two" states can be "fast" and "slow"; thus the phrase "first and second states" is indefinite. Finally, applicant argues that moving the belt in a direction to tighten the belt around a patient's chest is clear, yet Fig. 9 does not enhance the understanding of how this is done but rather provides a confusing picture of how the belt can be possibly tightened. In particular, it would appear to be impossible for the cable (256) as shown in Fig. 9 as being perpendicularly attached to the belt as being able to tighten up the belt by actuating the cable.

As to the claims, applicant argues that Dedo does not disclose a CPR device that sits on the chest. Dedo discloses a respiratory assist device having a strap (24) that sits on the chest wherein the cyclic compression forces provided by its belt could provide CPR. In particular, Dedo discloses that the device is disposed to cover a lower region of the rib cage. Since a chest is defined by the human body enclosed by the ribs and sternum, Dedo's device is clearly disposed on the chest near the sternum. Examiner respectfully disagrees with Applicant in that Dedo would cause a backflow of blood toward the heart or that DEdo provides continuous pressure to the abdomen. Instead Dedo, just like the instant invention, can compresses the chest cyclically to

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assist respiration and provide CPR assistance. Applicant also argues that Dedo's belt (46) has no active function but this is irrelevant since it is Dedo's strap (24) that is tightened and released about a patient's chest to assist in respiration and the CPR process. Applicant also argues that there is no suggestion to combine Dedo with Szpur. As stated in the last office action, Szpur provides a timed application of force to tighten a belt around a user. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine Szpur's belt tightening mechanism with Szpur's strap (24) to allow for electrically controlled compression of a patient's chest.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAM NGUYEN whose telephone number is (571)272-4979. The examiner can normally be reached on Monday - Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on 571-272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

April 13, 2009

/Tam Nguyen/
Examiner, Art Unit 3764

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764